



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT - 1 1997

Mr. Thomas W. Peterson
Vice President, General Manager
Pharmaton Natural Health Products
900 Ridgebury Road
P.O. Box 368
Ridgefield, Connecticut 06877

0565 '98 MAR 24 P2:44

Dear Mr. Peterson:

This is in response to your letter of September 21, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Pharmaton Natural Health Products is making a number of claims for "VENASTAT SUPRO Caps," a standardized horse chestnut seed extract. These claims, among other things, claim that the product "Helps Protect Against Leg Swelling" and is "...a natural way to support leg vein health and protect against lower leg swelling by improving the circulation in the leg veins."

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, taken together, suggest that it is intended to treat or prevent a disease, namely abnormal venous blood flow in the legs which results in lower limb swelling. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET121

Page 2 - Mr. Thomas W. Peterson

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, KCarson)
HFS-456 (r/f, Moore)
HFS-450 (r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
r/d:HFS-456:RMoore:9/23/97
Init:GCF-1:PDerfler:9/25/97
f/t:HFS-456:rjm:9/25/97:docname:54823.adv:disc22

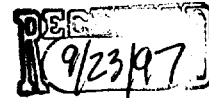
PHARMATON
NATURAL HEALTH PRODUCTS

Thomas W. Peterson
VICE PRESIDENT, GENERAL MANAGER

September 21, 1997

VIA HAND DELIVERY

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204



Re: VENASTAT™ Supro® Caps

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products, Division of Boehringer Ingelheim Pharmaceuticals, Inc., wishes to notify the Food and Drug Administration that within the past 30 days the company has begun marketing a dietary supplement with a label which bears statements of nutritional support.

The dietary supplement for which the statements are made is VENASTAT™ Supro® Caps, which consist of Standardized Horse Chestnut Seed Extract 300 mg (aesculin free). The statements of nutritional support read as follows:

Dietary Supplement for Leg Health

Promotes Leg Vein Health

Helps Maintain Leg Vein Circulation

Helps Protect Against Leg Swelling

... has been shown through extensive research to be a safe and beneficial way to supplement your diet for leg vein health

54823

Linda S. Kahl, Ph.D.
September 21, 1997
Page 2

... a natural way to support leg vein health and protect against lower leg swelling by improving the circulation in the leg veins

VENASTAT will help you maintain good venous blood flow in your legs.

A copy of the package and container label for each size (30 and 60) of the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. (The disclaimer is in bold print in a box.)

The Company certifies that it possesses adequate substantiation for these statements of nutritional support which renders the statements truthful and non-misleading, and thus permissible under the DSHEA.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas W. Peterson", with a stylized, flowing script.

Thomas W. Peterson

Enclosures

VENASTAT™

60 SUPRO® CAPS

8A3940

STANDARDIZED HORSE CHESTNUT SEED EXTRACT
VENASTAT™

NEW!

STANDARDIZED HORSE CHESTNUT SEED EXTRACT

VENASTAT™

DIETARY SUPPLEMENT FOR LEG HEALTH

- Promotes Leg Vein Health
- Helps Maintain Leg Vein Circulation
- Helps Protect Against Leg Swelling

60 SUPRO® CAPS
300 Mg each

DIETARY SUPPLEMENT FOR LEG HEALTH

VENASTAT™

STANDARDIZED HORSE CHESTNUT SEED EXTRACT

STANDARDIZED HORSE CHESTNUT SEED EXTRACT

VENASTAT™

DIETARY SUPPLEMENT FOR LEG HEALTH

8A3910

STANDARDIZED HORSE CHESTNUT SEED EXTRACT
VENASTAT™

NEW!

STANDARDIZED HORSE CHESTNUT SEED EXTRACT

VENASTAT™

DIETARY SUPPLEMENT FOR LEG HEALTH

- Promotes Leg Vein Health
- Helps Maintain Leg Vein Circulation
- Helps Protect Against Leg Swelling

30 SUPRO® CAPS
300 Mg each

DIETARY SUPPLEMENT FOR LEG HEALTH

VENASTAT™
STANDARDIZED HORSE CHESTNUT SEED EXTRACT

STANDARDIZED HORSE CHESTNUT SEED EXTRACT
VENASTAT™

30 SUPRO® CAPS

VENASTAT™